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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/051,098 | 01/22/2002 | Youji Sakagami | 4853.0023-02 | 4190 |
| 22852 | 7590 | 01/30/2004 | | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005 | | | EXAMINER GUPTA, ANISH | |
| | | | ART UNIT 1654 | PAPER NUMBER |

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/051,098

Applicant(s)

SAKAGAMI ET AL.

Examiner

Anish Gupta

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Terminal Disclaimer

The terminal disclaimer filed on 9-23-03 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,004,906 has been reviewed and is NOT accepted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 18-19 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

For claim 18, Applicants assert that the written description for a product by process claim can be fulfilled by the process of making the compound. Applicants rely on Amgen v. Chugai Pharmaceutical Co., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991) and Fiers v. Revel, 25 U.S.P.Q.2d 1601 (Fed. Cir. 1993) and assert “under these two pre-Lilly decision product-by-process claims do not need further recitation of structure, name, formula, or definitive chemical or physical properties.”

Applicants argue that claim 19, contrary to the rejection, expresses the physical properties of the claimed peptides. Applicants state that description of a generic can be achieved by not only by partial structure, but also physical properties, citing Lilly 43 U.S.P.Q.

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2d at 1566. Applicants make a distinction from function and physical properties by stating that functional language is what a peptide does. Applicants assert that the peptide is described by physical properties. It is acidic, which can be measured by litmus test, it is soluble which is a well-recognized physical property, and it is polar. Applicants also state that there is no requirement on the Applicants to describe all of the species that claim encompasses to fulfill the written description.

Applicant's arguments filed 9-2303 have been fully considered but they are not persuasive.

It is acknowledged that the MPEP recognizes that for a product by process claim, the written description can be fulfilled by the process used to produce that product. However, the Federal Circuit has also stated that description requirement may not be satisfied for a class of compounds, "even though the specification might have indirectly enabled one skilled in the art to make and use the entire class. . . . [I]t is possible for a specification to enable the practice of an invention as broadly as it is claimed, and still not describe that invention." Application of DiLeone, 436 F.2d 1404, 1405 (C.C.P.A. 1971). The Court went on to state, in a footnote that, "consider the case where the specification discusses only compound A and contains no broadening language of any kind. This might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been described." Id. This is rather analogous to the instant application. Applicants have described only a small number of species and a method of making these compounds. The method of making might be enabled to make the entire class desired, but the entire class has not been described to the extent that one could

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conclude that Applicant was in possession of the claimed invention. Furthermore, in Fiers, the Court stated that for a product claim drawn to a DNA, "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Fiers 984 F.2d at 1170. Thus, even the Fiers court recognized that adequate written description required more than just potential method of obtaining it. Rather, it required the structure itself. Here, the Applicants have failed to provide any guidance as to the structure of the claimed peptide and thus fail the written description requirement, even though the claims are drawn to a product by process claim. One cannot conclude that Applicants were in possession of the genus even where they have disclosed a potential method of obtaining it.

For claim 19, while it is true that a broad generic can be described by physical properties, it is settled that these physical properties must distinguish the claimed invention from other material. The MPEP states that a genus can be described by "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

The fact that the peptide is soluble, acidic, and polar does not provide ample description to distinguish it from other material. As stated in the previous office action, properties such as the peptide is acidic and polar; only implies that there is higher number of

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acidic and polar amino acid, such as aspartic acid, glutamic acid, tyrosine, cysteine, Asparagine, glutamine, serine, and threonine, present. However, the number of these amino acids can vary since the claim does not recite an amino acid length for the growth factor. The presence of these types of amino acids does not lead one to conclude that the applicant was in possession of the claimed invention.

Applicants state that they do not need to disclose the entire scope of the species to fulfill written description. This is indeed true, but Applicants none the less have to show a “representative number” of species that fall within the broad generic. This has not been achieved. Applicants have only described a small number of peptides that have a common core with the presence of tyrosine in the first and third position. The disclosure of these peptides do not qualify as a “representative number” as required by the MPEP. Satisfactory disclosure of a “representative number” depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. Given the breadth of the claims, one of ordinary skill in the art can not conclude that the Applicant was in possession of the entire genus since one could not conclude what the necessary common attributes or feature of the elements possess by the members of the genus.

The rejection is maintained.

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

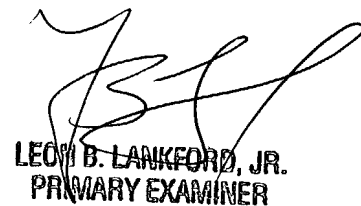
3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Anish Gupta



LEON B. LANFORD, JR.
PRIMARY EXAMINER